



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

11225711

Certified/Return Receipt Requested

December 10, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Timothy P. Cody, Chief Executive Officer
Freed's Pharmacy, Inc.
6394 College Blvd.
Overland Park, KS 66211

KAN #99-006

Dear Mr. Cody:

Recently an inspection was made of your liquid medical oxygen transfilling operation located at the above address. This inspection was conducted on November 18 & 23, 1998, by a Food and Drug Administration Investigator from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the liquid medical oxygen transfilled at this location to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

failure to consistently conduct release testing, i.e., identity and potency, on the first filled vessel from new product in stand tank, in that there are no records kept of this operation since March 2, 1998 [21 CFR 211.165(a)];

failure to conduct periodic audits of your liquid oxygen supplier, and failure to have a written procedure to cover such audits [21 CFR 211.84(d)(3) & 211.100];

failure to consistently and adequately calibrate the oxygen analyzers used in your liquid oxygen transfilling operation [21 CFR 211.68(a) & 211.160(b)(4)];

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failure to establish adequate batch production and control records for each batch of liquid medical oxygen transfilled, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)].

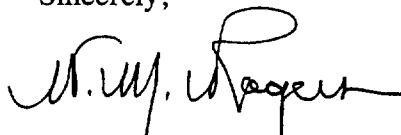
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. We are enclosing a copy of the Form FDA 483 which was issued to Mark A. Ubert, Chief Financial Officer, at the conclusion of the inspection.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your liquid medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", with a stylized flourish at the end.

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483